REMARKS

Claims 1, 2, 4, 7, 10, 15, 17-18, 20-22, and 29 are currently amended. New claims 30-31 have been added. Claims 1-31 are active.

The limitations of previously presented claim 20 have been moved to new dependent claims 30 and 31.

Claims 1, 2, 4, 15, 17, and 22 have been amended to remove unnecessary parentheticals and/or correct typographical errors. Minor amendments have been made to claims 10, 18, and 21 to clarify the claim language.

Claims 7 and 17 have been amended to specify microcrystalline cellulose instead of compression aid so that they properly depend from claim 1.

Applicants submit that no new matter has been added by these amendments.

Applicants thank the Examiner for entering the amendments in the reply filed May 14, 2007.

Rejection under 35 U.S.C. § 103(a) over Gantt in view of Sheth or Remington, further in view of Oshlack

The Examiner has rejected claims 1-5, 7-27, and 29 over WO 01/43725 A1 to Gantt et al. ("Gantt") in view of U.S. Patent No. 4,954,349 to Sheth et al. ("Sheth") or an excerpt on oral solid dosage forms from the 19th edition of Remington's The Science and Practice of Pharmacy (1995) ("Remington"). The Examiner has rejected claims 6 and 28 over Gantt in view of Sheth or Remington and further in view of U.S. Patent No. 5,472,712 to Oshlack et al. ("Oshlack"). Applicants respectfully traverse these rejections.

Applicant first notes that neither Gantt nor Sheth meet the limitation that "the tablet hardness is at least about 14 kP," acknowledged by the Examiner on page 4 of the February 13, 2007 Office Action. Gantt is silent on hardness values, and the tablets in Sheth have hardness values of only 7-12 kP (col. 8, Examples 4 and 5). The Examiner incorrectly asserts that "the burden is shifted to applicant to show that the compressed tablet of Gantt does not exhibit the claimed properties. . . ." No such burden applies here; rather, obviousness cannot be predicated on a property inherent or unknown at the time of the invention. MPEP § 2141.02. Thus, Applicant submits that this claim limitation has not been met by the references combined.

Even if inherency could be used to establish obviousness, the Examiner uses an improper hindsight analysis by combining Gantt and Sheth to arrive at the claimed invention.

In simple terms, Applicants' invention comprises a potassium chloride crystal surrounded by two distinct layers to form a microcapsule; once formed, these microcapsules are mixed with other excipients to prepare a compressible blend that is pressed into tablets. Colloidal silicon dioxide is one of the excipients added to the fully formed microcapsules in the compressible blend. By including colloidal silicon dioxide[1], Applicants have found that they can consistently achieve tablets with superior hardness and friability properties compared to those without colloidal silicon dioxide. *See* Examples 10-13 in accordance with aspects of the invention.[2]

Gantt also teaches potassium chloride tablets, but Gantt's tablets do not contain colloidal silicon dioxide, as the Examiner acknowledges. *See* February 13, 2007 Office Action at 3.

The Examiner relies on Sheth to cure this deficiency in Gantt. Sheth, however, discloses colloidal silicon dioxide in a single place in the specification as one possible excipient in a very long list of broadly defined conventional adjuvants and excipients. Col. 5, ll. 46-57. It is well settled that some motivation to select the claimed species must be taught in a reference disclosing a broad genus.[3] Nothing in Sheth suggests that colloidal silicon dioxide is preferred over the myriad other excipients listed. In fact, Sheth teaches that magnesium stearate and/or talc are preferred lubricants by incorporating them into all of the examples of microcapsules and/or tablets. *See* Examples 2-6. Thus, the most reasonable modification of Gantt would be to select one of the preferred lubricants from Sheth (*i.e.,* magnesium stearate or talc) rather than colloidal silicon dioxide. Indeed, Applicants submit that only hindsight informed by Applicants' disclosure would motivate one of ordinary skill in the art to pluck out colloidal silicon dioxide from the "laundry list" of excipients in Sheth.

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[1] Applicants note that "colloidal silicon dioxide" (or colloidal silica) is a particular form of silica, with a very small particle size ranging from 1-100 nm, and differs from non-colloidal silica in various ways, including: (1) its suspension properties; (2) its liquid form (as opposed to powder); and (3) its wide-ranging and high specific surface area. *See, e.g.,* "Questions and Answers" on the Eka Chemicals/Industrial Specialties website, http://www.colloidalsilica.com.

[2] In particular, compare Example 10 (with colloidal silicon dioxide) and Comparative Examples 4-6, illustrating that incorporating colloidal silicon dioxide into the compressible blend results in the same high values of hardness but decreases undesirable friability approximately 10-fold.

[3] *See In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

Moreover, Applicants note that Sheth could be combined with Gantt in a number of different ways which would not provide the claimed invention. For example, Sheth teaches a potassium chloride microcapsule with a single layer surrounding the potassium chloride crystal, not the two distinct layers of the instant claims. Thus, one could as readily combine Gantt and Sheth to provide a single coating on the potassium chloride (rather than the two coatings of the claimed tablet), rather than the combination proposed by the Examiner. Thus, only with the benefit of hindsight would one of ordinary skill in the art arrive at the modification asserted by the Examiner.

The Examiner relies on Remington for its teaching of "the use of silicon dioxide in compressed tablet." February 13, 2007 Office Action at 3. This reliance suffers from the same problem as Sheth, only amplified. Remington is an encyclopedic compendium listing virtually all possible ingredients for oral dosage forms, without recommending any combinations. Simply selecting the particular excerpt cited is an act of hindsight; Applicants submit that the Examiner could not reasonably select the portion of Remington to cite without the guidance of Applicants' disclosure. The Remington excerpt, of course, provides no teaching on how or when to combine colloidal silica with other ingredients. And Remington's silence does not overcome the countervailing teachings of Sheth's to use magnesium stearate and talc as excipients. Thus Remington cannot compensate for the deficiency of Gantt.

Neither does Oshlack fill the gap in Gantt. The only place where Oshlack even mentions colloidal silicon dioxide is in one of 29 examples (Example 13, col. 31, ll. 8-11 and Table 33), where it is used in the coating of a drug-coated sphere, not as an excipient in the compressible blend. Even if Example 13 could be seen as a "teaching," Oshlack clearly recommends other excipients for the compressible blend, contemplating only metal stearates and identifying magnesium stearate as most preferred.[4] *See* Col. 15, ll. 5-11.

Applicants submit that if the combined references teach anything about colloidal silicon dioxide, they teach that it is a non-preferred excipient, inferior to magnesium stearate, to be

[4] The relevant passage of Oshlack reads: "Also, an effective amount of any generally accepted pharmaceutical lubricant, including the calcium and magnesium soaps may be added to the above-mentioned agents of the excipient prior to compression of the tablet core agents. Most preferred is magnesium stearate in an amount of about 0.2-3% by weight of the solid dosage form." Col. 15, ll. 5-11.

optionally included in the coating of the microsphere but not in the compressible blend. These combined teachings would not prompt one of ordinary skill in the art to select colloidal silica in the first place, let alone incorporate it into a different part of the tablet (*i.e.*, as a component of the compressible blend) rather than in the coating, as disclosed by Oshlack.

Accordingly, the rejection under Section 103 is improper, and Applicants request that it be withdrawn.

Applicants respectfully submit that the claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

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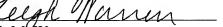
By: 
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